UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

JOANNE MACSWAN Plaintiff, v. MERCK & CO., INC., Defendant.	Case No. 1:20-cv-01661-CCR

DEFENDANT'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS AS TO THE DESIGN DEFECT CLAIMS IN COUNTS I AND II, AND AS TO COUNTS III, IV, V, AND VI OF PLAINTIFF'S COMPLAINT

In her Opposition, Plaintiff accurately summarizes Merck's arguments as characterizing her as "a zebra in a land of horses." ECF 18-2, Pl's Mem. at 1. Indeed, she is a zebra alone in a land where all the other horses have come and gone:

- First, by Plaintiff's own admission, Merck warned of the risk of ONJ as early as 2005. Id. at 2. See also ECF 1-1, Compl. ¶ 33. Plaintiff alleges that she "began taking [Fosamax] in January 2009," Id. ¶ 40—nearly four years later. And, she filed this lawsuit more than fifteen years after Merck's implementation of that FDA-approved warning.

- Second, unlike Plaintiff here, the overwhelming majority of the claimants in the ONJ MDL that Plaintiff references, Pl's Mem. at 1, used Fosamax and allegedly sustained their injury *before* Merck and the FDA implemented the 2005 Warning.

- Third, in 2013, eight years after the Warning, and five years after Fosamax became available in generic form, the parties to that ONJ MDL reached a settlement in principal of the entire MDL. Plaintiff's lawsuit is the only action against Merck for ONJ-related injuries filed within the last five years.

- Fourth, given these differences, it cannot be alleged that Plaintiff asserts "identical" claims to those in the MDL proceeding. See Pl's Mem. at 1. Despite Plaintiff's claim that "countless public documents" and other Fosamax cases weigh against granting judgment on the pleadings, Plaintiff failed to cite a single decision helpful to her cause.

I. ARGUMENT

A. Plaintiff's design defect claims (Counts I and II) fail to allege the existence of a feasible alternative design and are otherwise preempted by federal law.

1. Plaintiff has not alleged the existence of a feasible alternative design.

Plaintiff concedes that to prevail on a design defect claim, New York law requires "a plaintiff to prove . . . it was feasible to design the product in a safer manner." Pl's Mem. at 5. As a necessary element of any design defect claim, courts thus require a plaintiff at the pleading stage to allege the existence of a feasible alternative design. See ECF 17, Merck's Mem. at 7-8 (collecting cases). If a plaintiff fails to do so, his or her case is routinely dismissed. See id.

Attempting to avoid that result here, Plaintiff appears to argue: (1) that she need not allege a feasible alternative design as that would require her "to possess technical or scientific knowledge

about the inner workings of the product;" and (2) that alternatively, she has alleged a feasible alternative design because Fosamax purportedly "could have been designed without nitrogen." Pl.'s Mem. 6 (citations and internal quotation marks omitted). Plaintiff is mistaken on both fronts.

Plaintiff's reliance on Ohuche v. Merck, 2011 WL 2682133 (S.D.N.Y. July 7, 2011) is misplaced because the plaintiff in that case proceeded *pro se*. See 2011 WL 2682133, at *2 ("submissions of a pro se litigant should be held to less stringent standards than formal pleadings drafted by lawyers") (footnote and internal quotation marks omitted). Courts have recognized that fact and have refused to follow Ohuche when the plaintiff is represented by counsel.[1] Moreover, although the Court in Sullivan v. Aventis, Inc. held that requiring a plaintiff to allege in granular detail the precise makeup of the allegedly feasible alternative design "would require the plaintiff to possess technical or scientific knowledge about the inner workings of the product," it nonetheless required the plaintiff to plead allegations sufficient to put the defendant "on notice of the nature of the Plaintiff's claims." 2015 WL 4879112, at *7 (S.D.N.Y. Aug. 13, 2015) (internal citations omitted). In so holding, the Court noted that the plaintiff "ha[d] pleaded greater detail than [] plaintiffs" whose claims were subject to dismissal for failing allege a feasible alternative design. Id.

Here, Plaintiff's lack of *any* details concerning an allegedly feasible alternative design renders her case distinguishable from Sullivan and analogous to the decisions Merck cites in which design defect claims were dismissed. Merck's Mem. at 7-8. Indeed, Plaintiff's newfound contention (raised for the first time in her Opposition[2]) that she "alleges that [Fosamax] could have been

[1] See Kennedy v. Covidien, LP, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019) ("The particular circumstances in Ohuche cannot be read to undermine the general requirement that an alternative design must be pleaded, even if it is not fully developed at the pleading stage."); Koublani v. Cochlear Ltd., 2021 WL 2577068, at *11 (E.D.N.Y. June 23, 2021) (same).

[2] Allegations not contained in Plaintiff's Complaint cannot be considered when resolving this motion. See, e.g., K.D. ex rel. Duncan v. White Plains Sch. Dist., 921 F. Supp. 2d 197, 2089 n.8 (S.D.N.Y. 2013) ("however, there are no allegations in the pleadings to support this argument. Plaintiffs cannot amend their complaint by asserting new facts or theories for the first time in opposition to Defendants' motion to dismiss") (citation omitted).

designed without nitrogen" is telling: it is made ***without citation*** as the allegation is absent from her Complaint, and not in admissible form in her Memorandum of Law. See Pl's Mem. at 6.

Finally, Plaintiff contends that it "would be unreasonable" to require her to plead an alternative feasible design at the pleading stage because Merck is already on notice of her claims since it "previously litigated MDL proceedings involving thousands of similar plaintiffs." Id. at 6-7 & n.3. By Plaintiff's own representation, however, she had access to and could have reviewed "countless public documents" and "thousands" of claims from that MDL. Id. at 1. If any one of those claimants had adequately pleaded a feasible alternative design, Plaintiff surely would have included that alternative design in her Complaint. Instead, Plaintiff identifies no pleading in the ONJ MDL that alleged a feasible alternative design.[3] Merck is therefore not already on notice of "the nature" of Plaintiff's design defect claim, id. at 7 n.3, and the Court should dismiss her claims for failing to plead a feasible alternative design as required by New York law.

2. Plaintiff's design defect claims are preempted by federal law.

Plaintiff's preemption analysis is erroneous. See id. at 7-8.

First, she incorrectly contends that Merck's reliance on Mutual Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013), is "misplaced as that case involved a generic drug" and, as a result, "has no impact on *brand-name* manufacturers." Pl's. Mem. at 7. Contrary to Plaintiff's position, the distinction between generic and branded manufacturers is only relevant in the context of a failure to warn claim;[4] it is irrelevant in the context of a design defect claim because "[o]nce a drug—

[3] Again, that MDL overwhelmingly involved claimants who began taking Fosamax and allegedly sustained injury before the 2005 ONJ warning took effect and whose claims thus principally focused on an alleged failure to warn.

[4] The distinction between a branded and generic manufacturer is relevant in the context of a failure to warn claim because a branded manufacturer can, under certain circumstances, update its drug label without prior FDA approval pursuant to the FDA's "changes being effected" ("CBE") regulation. And if a plaintiff can demonstrate that a defendant manufacturer could have utilized the CBE process, his or her failure to warn claim is not preempted. See, e.g., In re Zantac (Ranitidine) Prods. Liab. Litig., 512 F. Supp. 3d 1278, 1294 (S.D. Fla. 2021) ("Because the CBE process enables brand-name drug manufacturers to strengthen warnings on labeling without waiting for FDA approval, a

whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Bartlett, 570 U.S. at 477 (emphasis added) (citation omitted). Plaintiff fails to even address the cases cited by Merck that expressly relied upon Bartlett to hold that design defect claims against branded manufacturers were preempted by federal law. See Yates, Inc., 808 F.3d at 300 (holding under New York law that plaintiff's "post-approval design defect claims are preempted by federal law"); Merck's Mem. at 9-12.

Second, Plaintiff's reliance on Wyeth v. Levine, Pl's. Mem. at 7, is misplaced as that case dealt strictly with a failure to warn claim and the branded manufacturer's ability to update its drug label through the CBE process. See 555 U.S. 555, 573 (failure to warn claim not preempted because "[t]he CBE regulation permitted Wyeth to unilaterally strengthen its warning"). Again, the preemption inquiry applicable to a failure to warn claim is irrelevant in the face of a design defect claim. See In re Zantac (Ranitidine) Prod. Liab. Litig., 512 F. Supp. 3d at 1294 ("As with generic drugs, a claim based on an allegation that a brand-name drug's FDA-approved formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved.").

Third, Plaintiff asserts another new argument for the first time in her Opposition, see supra note 2—that "Merck could have long ago produced a safer drug and gained FDA approval for that drug." Pl.'s Mem. at 7-8. According to Plaintiff, "no federal law 'restricts a brand-name drug

labeling claim against a brand-name drug manufacturer is not necessarily pre-empted."). The same is not true, however, for generic manufacturers. Because a generic manufacturer "is responsible for ensuring that its warning label is the same as the brand name's," a generic manufacturer "may not" not utilize the CBE process; instead, generic manufacturers "may only change their labels 'to match an updated brand-name label or to follow the FDA's instructions.'" Utts v. Bristol-Myers Squibb Co., 226 F. Supp. 3d 166, 180–81 (S.D.N.Y. 2016) (citations and internal quotation marks omitted). As a result, failure to warn claims against generic manufacturers are preempted by federal law because they "could not have changed [the] label without prior FDA approval, which [they] could have obtained only by proposing that the FDA require a change in the corresponding brand name label." Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 295 (6th Cir. 2015) (citation and internal quotation marks omitted).

manufacturer from designing a reasonably safe product prior to FDA approval." Id. at 8 (citation omitted).[5] Plaintiff is mistaken: courts have also rejected the pre-approval design defect theory as an impermissible end-around preemption. See, e.g., Yates, 808 F.3d at 300 (holding under New York law that plaintiff's "pre-approval and post-approval design defect claims are preempted by federal law").[6]

B. Plaintiff concedes that her express warranty claim (Count III) is deficient by relying exclusively on conclusory allegations.

New York law is unequivocal: "to state a claim for breach of express warranty, the injured party must identify in the complaint the 'specific words, promises or statements' made by the defendant" and "provide detail about '*where, when* or *how* the alleged promise[s] or statement[s] [were] provided.'" Hume v. Lines, 2016 WL 1031320, at *5 (W.D.N.Y. Mar. 8, 2016) (citations omitted). A failure to provide that vital information "is fatal to the claim." Id.

Adhering to the same formulaic recitation of the elements contained in her Complaint,[7] Plaintiff's conclusory allegations fail to provide the level of specificity required by New York law. See Merck's Mem. at 12-13. Nowhere in her Complaint does Plaintiff identify the specific words or promises allegedly made by Merck; where or how those statements were purportedly made; or

[5] Even assuming Plaintiff's position is correct, her Complaint fails to set forth any allegations that could amount to a pre-approval design defect claim. At best, she alleges that Merck could have utilized "alternative safer products." See Compl. ¶ 36 ("Consumers, including Ms. MacSwan, who used [Fosamax] . . . had several alternative safer products available to treat their conditions."); id. ¶ 61 ("Further, [Fosamax] posed a greater risk than other similar medications"). Plaintiff cannot satisfy her burden to propose a feasible alternative design by simply "proposing that an entirely different product could have been used." See Merck's Mem. at 8-9 (citations and internal quotation marks omitted).

[6] See also Gustavsen v. Alcon Lab'ys, Inc., 272 F. Supp. 3d 241, 254-55 (D. Mass. 2017) (finding "the Sixth Circuit's conclusion in *Yates* more consistent with" [*Mensing*] and *Bartlett*, and stating that "defendants here could not have marketed [eye] droppers ... in the manner plaintiffs advocate without the FDA's prior approval" and that it was "irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted"), aff'd, 903 F.3d 1 (1st Cir. 2018); Brazil v. Janssen Rsch. & Dev. LLC, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016) ("This original design theory of liability makes little sense in the face of the Supreme Court's precedents . . . . indeed, it is unclear how any of the lawsuits in Bartlett, Mensing, or Levine could have even had an issue with preemption if the duty required by state law covered the original design.").

[7] See Pl.'s Mem. at 9 (Plaintiff asserting that she has satisfied New York's pleading requirements by generically alleging: (1) that "Merck represented to MacSwan and her doctors that [Fosamax] 'had been adequately tested, was to be prescribed in accordance with its intended uses, was of merchantable quality, and was not dangerous;'" and (2) that those "statements were made to MacSwan and her physicians through advertising and other materials.").

when those statements were purportedly made. Plaintiff's rebuttal that the statements were made "through advertising and other materials" is woefully deficient. Pl's Mem. at 9. It leaves Merck without notice as to the specific advertisements and materials Plaintiff or her physicians purportedly received, the contents of those materials, and when they received them. This information is "peculiarly within the possession of *Plaintiff*" or her physicians and should have been included in her Complaint. See Merck's Mem. at 13 (citation and internal quotation marks omitted).

C. Plaintiff failed to rebut Merck's authority dictating that her breach of implied warranty claim (Count IV) should be dismissed.

1. Plaintiff's breach of implied warranty claim fails as a matter of law because it is based on an inadequately pled and/or preempted design defect claim.

Plaintiff does not address any of the authority cited in Merck's motion that supports the conclusion that Plaintiff's breach of implied warranty "fails as a matter of law" because she has also failed to plead the elements necessary to support a design defect or manufacturing defect claim. Merck's Mem. at 14. Instead, Plaintiff primarily relies on Caronia v. Philip Morris USA, Inc., 715 F.3d 417 (2d Cir. 2013) and Denny v. Ford, 87 N.Y.2d 248 (1995). Pl's Mem. at 10.

Caronia and Denny, however, are consistent with Merck's position. Indeed, the Court in Morrison v. Hoffmann-La Roche, Inc., relied upon Caronia when holding that because "Plaintiff's defective design claim fails . . . , the breach of implied warranty claim fails as well." 2016 WL 5678546, at *11 (E.D.N.Y. Sept. 29, 2016). These cases instead dictate that when a plaintiff's breach of implied warranty claim is based on the same factual allegations as a defectively pled design defect claim, the warranty claim also fails. See Nemes v. Dick's Sporting Goods, Inc., 2021 WL 739032, at *11-12 (S.D.N.Y. Feb. 23, 2021). Thus, such a claim in a products liability case "can only survive to the extent the 'ordinary purpose' for which the product was sold and marketed is not the same as the purpose that provides the utility that outweighs the risk of injury." Id.

(citation omitted). See also Denny, 662 N.E.2d 730, 738-39 ("what makes this case distinctive is that the 'ordinary purpose' for which the product was marketed and sold to the plaintiff was *not* the same as the utility against which the risk was to be weighed").

That is not possible here as the "ordinary purpose" for which Fosamax is sold is the same purpose that provides the utility against which the risk is to be weighed: the prevention and treatment of osteoporosis. See Pl.'s Mem. at 10 ("When MacSwan was prescribed and began taking FOSAMAX, she expected the drug would prevent and treat osteoporosis, as Merck represented.") (citations omitted). Accordingly, Plaintiff's claim should be dismissed.

2. Plaintiff does not assert a breach of implied warranty claim based on an alleged failure to warn.

In a footnote, Plaintiff claims that she has asserted a breach of implied warranty claim based on Merck's alleged failure to warn and that because Merck is not moving for judgment on the pleadings with respect to her failure to warn claims, her corresponding breach of implied warranty claim based on failure to warn must survive. Id. at 10 n.5.

To be clear, Merck contends that Plaintiff's implied warranty claim should be dismissed in its entirety. Plaintiff concedes that "[t]o state a claim for breach of implied warranty, [she] must prove '(1) that the product was *defectively designed or manufactured* . . . .'" Id. at 9 (emphasis added). Thus, because Plaintiff does not allege a manufacturing defect in this case, she must necessarily satisfy the pleading requirements for a design defect claim. And because she has failed to do so, her claim should be dismissed. See, e.g., Oden v. Bos. Sci. Corp., 330 F. Supp. 3d 877, 895-96 (E.D.N.Y. June 4, 2018) ("as the Court has previously found that Plaintiff has failed to plead the necessary predicate elements to support his design and manufacturing defect claims, Plaintiff's breach of implied warranty of merchantability claim necessarily fails as a matter of law.") (citation omitted).

In any event, Plaintiff has failed to allege a breach of implied warranty claim based on an alleged failure to warn. Her claim is based solely upon the purported defective design of Fosamax. See Compl. ¶¶ 77-87. Plaintiff contends that Fosamax was not "merchantable" because it caused her to develop ONJ. Id. ¶¶ 78, 80, 82, 85 (alleging that Merck "manufactured" Fosamax, "impliedly warranted that [Fosamax] was of merchantable quality and fit for use in the medical community," and "breached its implied warranty to [Plaintiff] by manufacturing . . . a product" which caused her "significant and permanent injuries"). The fact that Plaintiff admits that Merck warned of the risk of ONJ as early as 2005—four years before she allegedly began taking the medicine—further compels the conclusion that Plaintiff's claims hinge upon the adequacy of the product's design. Consequently, Count IV should be dismissed.

D. Plaintiff effectively conceded that her fraud claims (Counts V and VI) are deficient by relying exclusively on conclusory, threadbare allegations.

Apparently conceding that she cannot satisfy the dictates of Rule 9(b), Plaintiff incorrectly claims that when the alleged fraud is based on omission, a plaintiff need not "specify the time and place because no act occurred." See Pl.'s Mem. at 11-12. But Keane v. Keane, cited by Plaintiff, expressly rejects her position: it provides that "[p]ursuant to Rule 9(b), the complaint must: "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) *state where and when the statements (or omissions) were made*, and (4) explain why the statements (or omissions) are fraudulent." 2010 WL 2900258, at *2 (S.D.N.Y. July 20, 2010) (emphasis added) (citation and internal quotation marks omitted).

Simply put, Plaintiff fails to respond to any of the caselaw cited by Merck—particularly Amos v. Biogen Idec Inc., 28 F. Supp. 3d 164 (W.D.N.Y. 2014) and Loewy v. Stuart Drug & Surgical Supply, Inc., 1999 WL 76939 (S.D.N.Y. Feb. 11, 1999)—which demonstrates that Plaintiff's threadbare allegations fail to satisfy the dictates of Rule 9(b). Nor does she provide any caselaw

of her own where these types of boilerplate allegations have held muster under Rule 9(b) in a products liability action. Her nonsensical[8] fraud claims should be dismissed with prejudice.

E. The Court should deny Plaintiff's request for leave to amend her Complaint.

This Court should deny Plaintiff's request for leave to amend her Complaint. See Pl's Mem. at 13. The parties are beyond the April 30, 2021 deadline for amendment of the pleadings set forth in the Case Management Order. ECF 11 ¶ 5. More importantly, Plaintiff has not demonstrated that amendment would not be futile. See Murray v. New York, 604 F. Supp. 2d 581, 589 (W.D.N.Y. 2009) ("As the record now stands, however, plaintiff has not sufficiently shown exactly what he seeks to add to his complaint in this regard, making it impossible for the Court to determine whether the proposed amendment would be futile.").

Plaintiff specifically seeks leave to amend "the date when she was first prescribed and began taking [Fosamax], which" she now claims "was in 2001, not 2009." Pl.'s Mem. at 13 n.7. Surely, however, Plaintiff and her counsel had access to her medical records prior to the filing of the Complaint and knew at that time, or certainly could have easily confirmed, the date of her first Fosamax use.

Regardless of that fact, Plaintiff has not demonstrated how amending her alleged dates of Fosamax use saves her otherwise deficient claims. Her design defect claims would still fail because she has not proposed an alternative feasible design and they remain preempted; her express warranty claim still fails because she has not identified a material statement amounting to a warranty, nor reliance on that statement; her implied warranty claim would still fail as contingent on a defectively-pled and/or preempted design defect claim; and her fraud claims would still fail for

[8] Plaintiff's alleges that she began taking Fosamax in 2009. Compl. ¶ 40. Plaintiff also concedes that Merck warned of the risk of ONJ as early as 2005. E.g., id. ¶ 33. She fails to explain how she could possibly hold Merck liable for the alleged concealment of a risk that she herself admits was publicized years before she began taking the medicine.

failure to satisfy the dictates of Rule 9(b). Plaintiff's request for leave to amend should therefore be denied, and this case should proceed solely on Plaintiff's remaining failure to warn claims.

II. CONCLUSION

For the foregoing reasons, Merck respectfully requests that its motion for judgment on the pleadings be granted with prejudice as to the design defect claims in Counts I and II and as to Counts III, IV, V and VI of Plaintiff's Complaint in the entirety.

Dated: October 1, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 1, 2021, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/s/ Robert G. Scumaci
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